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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,310	09/29/2003	Klaus Heilmann	2565/112	5354

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EXAMINER

MENON, KRISHNAN S

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/675,310

Applicant(s)

HEILMANN ET AL.

Examiner

Krishnan S. Menon

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 55-126 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 55-126 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 55-126 are pending as amended in the RCE of 2/21/06

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 55 -126 are rejected under 35 U.S.C. 102(b) as being anticipated by German Patent No. 3435883 (hereinafter referred to as GP (883)).

GP :883 teaches a dialyzer comprising a casing (12) containing hollow fibers and an end cap (24) attached to the casing (10) wherein the end cap (24) comprises a blood inlet channel (28) in axial direction relative to hollow fibers and curved members (50) arranged circumferentially and equidistant from each other to impart circular motion in a first direction (see figures 1-2). With regard to the first generally axial and second flow directions, the flow direction is axial at the inlet at 28, and then changes to radially outward through the curved members and then changes to radially inward under the member 46 – see flow direction arrow in the figure 1. With regard to the curved members being extending in the first direction away from an interior surface, the vanes extend from an interior surfaces (46 and 54) of the end cap in the axial direction. Please note that the member (46) can also be in the shape of a cone with its apex oriented towards the aperture (28) (see English translation, page 13, bottom

paragraph). This structure particularly reads on to the claim language 'curved member extending from an interior surface of the end cap that is adjacent to the channel in a direction same as the first generally axial direction'. Also see page 14, 3rd paragraph of the English translation, in which the elements (50) are described as serving as spacers that prevent the plate (46) from resting against the end cap, which means the elements (50) can be in physical contact with the surface (54) of the end cap as well, which would make the elements (50) as extending also from the surface (54).

Re claims 65,79,93,106 and 118: These claims add further, the limitation of "...the at least one member is integrally formed...". As can be seen in the figures of GP'883, the curved vanes (50) are integrally formed on the member 46 and which is fixedly attached to the end-cap and sealed to the housing; thus the end-cap forming an integral unit. Integral means 'a complete unit' ("formed as a unit with another part": Webster's Dictionary). Also, "...the use of a one piece construction instead of the structure disclosed in [the prior art] would be merely a matter of obvious engineering choice" (*In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965)). In addition, "integrally formed" denotes a process step of making the part, in which case, the *in re Thorpe* doctrine applies. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a

Art Unit: 1723

different process.” In re *Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

With regard to claims 121-126, the reference teaches the method of filtering by passing a fluid through the filter device; the filter device being a dialyzer, and the fluid being blood. See page 17 of the English translation.

Claims 68,82,96,109,120: These claims recite the sub-combination end cap or the combination filter device, which are taught by the reference – see figures. Channel from exterior to interior – 26. Flow path in the first direction – 28. A member located inside, and extending from the interior chamber – 46, which is straight or conical (see English translation, last paragraph in page 13) and provides a flow direction different from the first direction to the fluid. End cap includes two members – 54 and 46 – respective portions of which are spaced equidistantly, and the spacing between which decrease in the flow direction. The member 46 is also configured to impart a circular motion to the fluid due to the vanes on its surface.

2. Claims 55-67, 69,70,71,76-81, 83-95, 97-99,101,104-108,121 and 124 are rejected under 35 U.S.C. 102(b) as being anticipated by Hankammer (US 4,885,089).

Claim 55, 83: Hankammer teaches an end cap for a filter (title, figures 1,3) comprising a generally axial inlet flow path (9), curved members extending in the axial direction away from an interior surface of the end cap (4, figure 5) defining a flow radial direction for a fluid exiting the end cap as claimed.

Claims 69,97, 121, 124: Hankammer also teaches a filter in combination and a method of filtering by passing a fluid through a filter having such an end cap - (see column 2 lines 5-35).

Claims 56-58, 84-86: the end cap can be attached to a dialyzer; 'blood inlet channel' is intended use. A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987)

Claims 59-61, 87-89, 101: flow direction as claimed – see figures and column 2 lines 5-35)

Claims 62-67 and 76-81, 90-95, 104-108: the members are integrally formed, extends to the perimeter, arranged circumferentially around the channel, curved, radially symmetrical, equidistant to one-another, and the flow directions are as claimed – see figures.

Claims 70,71,98,99: the channel is an inlet channel – column 2 lines 5-35.
dialyzer and blood inlet channel are intended use – Ex parte Masham.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1723

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 55-67, 69-81, 83-95, 97-108, 110-119 and 121-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanno et al (US 4,201,673) in view of Hankammer'089..

Kanno teaches a dialyzer (figure 2 and abstract) comprising an inlet end cap, and plurality of hollow fibers as claimed with the inlet channel being blood inlet; and a method of filtering blood.

The teaching of Kanno differs from the claims in that Kanno does not teach the curved members extending from an interior surface that is adjacent to the channel of the end cap. Hankammer teaches an end cap for filter cartridges having an axial inlet and curved members integrally formed which are symmetrical and equidistant to one-another and render the flow from axial to radial as claimed. It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Hankammer in the teaching of Kanno for improved distribution of blood without channeling as taught by Hankammer (see column 2 lines 5-35). One would use the teaching of Hankammer in the teaching of Kanno because Kanno recognizes the need for proper distribution of blood without channeling and Hankammer teaches an improved structure for obtaining such distribution (Kanno column 3 line 45 – column 4 line 39).

Response to Arguments

Applicant's arguments filed 2/21/06 have been fully considered but they are not persuasive.

In response to the argument that Heilmann does not anticipate the claims because it fails to disclose the curved members extending from an interior surface of the end cap in a first direction, see the various different ways the reference anticipates this limitation in the rejection. Disk 46 in Heilmann forms an interior surface. The guiding vanes are extend away from the surface of 46 in the axial direction, and also from the surface 54 of the end cap, they are curved and direct the fluid radially. More over, the disc 46 can also be conical as shown in the rejection; and the vanes (50) can be in physical contact with surface 54, meeting the claim limitations. The vanes 50 would be extending away from the surface 54 as claimed, even if it has no physical contact with surface 54; however, the vanes do or can have physical contact as shown in the rejection.

With respect to the argument about the Hankammer reference, the reference reads on to the claims as shown, and therefore, it anticipates the claims. The argument about the water jet is misplaced: this description is for the intended use of the reference.

With respect to the argument that there is no motivation to combine the Kanno reference with Hankammer reference: motivation is shown in the rejection. In response to Applicant's arguments that, a person of ordinary skill in the art would not have been motivated to use the arrangement of Hankammer in the device of Kanno et al. because the device of Kanno et al. is not suitable to permit fluid flow in the manner in which fluid flows in Hankammer, i.e., through the sides of the device: the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the

Art Unit: 1723

structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Krishnan S. Menon
Patent Examiner
March 3, 2006